REMARKS

Reconsideration And Allowance Are Respectfully Requested.

Claims 17-20 and 23-44 are currently pending. Claims have 17, 18, 26, 27, 30 and 32 been amended. New claims 34-44 have been added. No claims have been canceled by way of the present amendment. Claims 1-16, 21 and 22 were previously canceled. No new matter has been added. Reconsideration is respectfully requested.

Based upon the prior amendment, the outstanding Office Action has withdrawn the previous rejection and inserted new grounds for rejection.

Applicant would first like to thank Examiner Nguyen for the courtesies extended during the interview conducted on August 27, 2009 with the undersigned attorney and with attorney Scott Kamholz.[1] During the course of the interview both the rejection under 35 U.S.C. § 112, first paragraph, and the rejection under 35 U.S.C. § 103 were discussed. Although an agreement was not reached regarding these rejections it was agreed the Examiner would reconsider the rejection based upon amendments and remarks presented in a subsequent amendment.

With regard to the outstanding rejections, claims 17-20 and 23-33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. With regard to claim 17, the Examiner indicates that the disclosure does not describe "consequently stimulating fibrosis of the vein at the treatment site, thereby permanently occluding the vein." Although Applicant believes that this claim recitation is supported by an enabling specification (see, for

[1] Reg. No. 48,543, not of record; attended the interview with the authorization of the undersigned attorney and with the consent of Applicant and Applicant's assignee.

example, page 5, line 2 et seq., where the underlying basics of sclerotherapy are disclosed and page 21, line 18, where the application of sclerotherapy to the present invention is discussed), Applicant has deleted the recitation in question to expedite prosecution. With regard to claim 25, the Examiner is referred to element 16 in Figure 1 as filed, which specifies a vessel size of 2-10 mm. Accordingly, Applicant respectfully request the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

With regard to the rejections based upon cited references, claims 17-19, 23, 24 and 26-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over R.A. Williams et al. ("Williams") in view of U.S. Patent Application Publication No. 2002/0188276 to Evans et al. ("Evans"). In addition, claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Williams in view of Evans, and further in view of U.S. Patent No. 6,048,332 to Duffy et al. ("Duffy"). Claim 25 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Williams in view of Evans based upon routine skill in the art. These rejections are respectfully traversed in view of the following remarks.

Claim 17 defines a method for permanently occluding a vein through the combined disruption of a vein vessel wall and application of sclerosant. The method includes advancing an elongated intraluminal member through the vein to a treatment site in the vein. The intraluminal member is thereafter moved against the vein's endothelium at the treatment site to disrupt the endothelium. A sclerosant is then injected into the vein at the treatment site and onto the damaged susceptible endothelium, thereby causing it irreversible damage at the treatment site.

In contrast, Williams discloses a sclerosant treatment. Basic sclerotherapy as disclosed by Williams is acknowledged in the Background of the Invention of the present application. However, and as the Office Action acknowledges, Williams "does not disclose advancing an elongated intraluminal member through the vein to a treatment site in the vein; moving activating the intraluminal member against the vein's lining at the treatment site to disrupt the lining".

The Office Action cites Evans for this proposition. However, Evans has nothing to do with sclerotherapy. In particular, Evans discloses an apparatus and method for clot dissolution. As discussed with the Examiner during a prior Interview, clot dissolution is very different from sclerotherapy. In particular, Evans is concerned with clot disruption and dissolution for the purpose of opening a passageway for the flow of blood through a vessel. Evans is not concerned with the treatment of varicose veins as contemplated by the claimed invention and Williams.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *In re Fine*, 873 F.2d 1071, 1073 (Fed. Cir. 1988). When assessing the obviousness of a claims invention, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR, International v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007). Evidence of a suggestion, teaching, or motivation to combine may come from the prior art references themselves, the knowledge of one of ordinary skill in the art, or in some cases, from the nature of the problem to be solved. *In re Dembiczak*, 173 F.3d 994, 999 (Fed. Cir. 1999). It is improper to base an obviousness conclusion on impermissible hindsight. *Id.*

The Examiner states that Evans teaches "advancing an elongated intraluminal member 12 through the vein to a treatment site in the vein (col. 2, paragraph 12); moving the intraluminal member against the vein's lining at the treatment site to disrupt the lining (paragraph 76)". However, this statement entirely mischaracterizes Evans. In particular, paragraph 76 states,

> Motor drive unit 14 includes a sliding switch 26 which controls the rotational speed of the motor and a sliding collar 28 which controls the axial position of an agitator 30 within a sheath 32 of the catheter body 12 (FIG. 2). A non-linear region 34 of the catheter body 12 is defined by the agitator 30 within the sheath 32. By axially translating the agitator 30 using the collar 28, the non-linear region of the catheter body can be moved in a proximal or distal direction along the catheter body. The motor drive unit will be capable of rotating the agitator 30 within the sheath 32 at the rotational rates set forth hereinabove. Additionally, the motor drive unit 14 may be adapted in other circumstances to oscillate the agitator, axially reciprocate the agitator, or provide for other mechanical movements of the agitator which can cause or contribute to clot disruption according to the methods of the present invention.

Nowhere in the disclosure does this indicate that the agitator disrupts or irritates the endothelium of the vessel wall. Rather, paragraph 76 states that rotation of the agitator "can cause or contribute to clot disruption according to the methods of the present invention". In fact, those with skill in the art would understand that in dissolving a clot, it would be highly desirable to prevent the agitator from disrupting the vessel endothelium. In fact, and as discussed during the prior Interview, Applicant is familiar with the device of Evans and can attest to the fact that the device of Evans is designed such that it is virtually impossible to irritate or disrupt the vessel endothelium with the agitator.

As such, it first would not be obvious to combine the teachings of Evans with the primary reference of Williams as these devices relate to very different medical procedures. In addition, Evans and Williams, in combination, fail to disclose each and every feature of the claimed invention.

Accordingly, Applicant respectfully requests that the rejection of claim 17 be withdrawn. With regard to those claims dependent upon independent claim 17, they are further to believed to overcome the cited references for at least the reasons discussed above.

In particular, and further with reference to the dependent claims previously rejected, the Examiner is mistaken in asserting that Williams or Evans discloses the claimed features. For example, neither reference discloses or suggests scraping the intraluminal member against the vein's endothelium (claim 18); neither reference discloses or suggests sclerosant injected through a hollow infusion wire (claim 19); neither reference discloses or suggests a balloon catheter disrupting the endothelium of a vein (claim 20); neither reference discloses or suggests withdrawing the intraluminal member while scraping and injecting sclerosant (claim 23); neither reference discloses or suggests an intraluminal member that disrupts the endothelium of a vessel and which is advanced through a sheath and the sclerosant is injected into the vein through an annular space between the intraluminal member and the sheath (claim 24); neither reference discloses or suggests a vein having a size at the treatment site of 2-10mm (claim 25, any rejection of which must include a reference in support of the contention of routine skill in the art rendering these limitations obvious); neither reference discloses or suggests scraping comprising rotating the intraluminal member in the vein under the control of a motor so that a portion of the intraluminal member engages the endothelium (claim 26); neither reference discloses or suggests an intraluminal member wherein a portion thereof is sharpened for engaging the endothelium of a vein (claim 27); neither reference discloses or suggests an intraluminal member disrupting the endothelium of a vein when the intraluminal member curves at a distal end (claim 28); neither reference discloses or suggests an intraluminal

member disrupting the endothelium of a vessel wherein the intraluminal member is simultaneously rotated and moved longitudinally (claim 29); neither reference discloses or suggests the fact that sclerosant is injected during moving (claim 30); neither reference discloses or suggests that the intraluminal member is rotated and moved longitudinally during scraping (claim 31); neither reference discloses or suggests wherein the vein's endothelium is disrupted without perforating the vein (claim 32); neither reference discloses or suggests wherein the intraluminal member disrupts the endothelium by moving longitudinally (claim 33) neither reference discloses or suggests wherein the sclerosant is injected during scraping (claim 34).

In addition to claims 17, 18, 19, 20 and 23-33, new claims 34-44 have been added. These new claims are believed to also overcome the cited references for reasons similar to those discussed above.

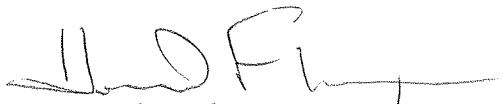
In summary,

- Evans' procedure is to open a blood vessel and the claimed invention is to occlude (close) a blood vessel.
- In Evans the patient has a blocked or closed vessel and they open it. In accordance with the claimed invention, the patient is cured, or needs no treatment, if the vessel is closed.
- The sclerosant used in accordance with the claimed invention is diametrically opposite in chemical/biological action to the drugs in Evans; Evans discloses dissolving drugs and the claimed invention employs a non-dissolving sclerosant.

- The mechanical action on the vein wall is diametrically opposite - wall damage is good in accordance with the claimed invention, while no (or as little as possible) wall damage is good in Evans.
- Williams' procedure is to close a blood vessel so combining Evans and Williams is inappropriate.
- The claimed invention different from Williams, as Williams does not teach mechanical vein wall damage to enhance sclerosant treatment.

It is believed that this case is in condition for allowance and reconsideration thereof and early issuance is respectfully requested. If it is felt that an interview would expedite prosecution of this application, please do not hesitate to contact Applicant's representative at the below number.

Respectfully submitted,



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